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U S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE 19141.0048U2 TRANSMITTAL LETTER TO THE UNITED STATES US APPLICATION NO (IF KNOWN, SEE 37 CFR DESIGNATED/ELECTED OFFICE (DO/EO/US) 10/018913 CONCERNING A FILING UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED 15 June 2000 18 June 1999 PCT/US00/16576 TITLE OF INVENTION LIGHT BEAM GENERATION AND FOCUSING DEVICE APPLICANT(S) FOR DO/EO/US Kumar et al. Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a FIRST submission of items concerning a filing under 35 U S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U S.C. 371. 2. This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay 3. examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 4.  $\boxtimes$ A copy of the International Application as filed (35 U.S.C. 371 (c) (2)) 5. is transmitted herewith (required only if not transmitted by the International Bureau). has been transmitted by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). A translation of the International Application into English (35 U.S.C. 371(c)(2)). A copy of the International Search Report (PCT/ISA/210). 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3)) 8. are transmitted herewith (required only if not transmitted by the International Bureau). have been transmitted by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. П have not been made and will not be made. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)). 10. A copy of the International Preliminary Examination Report (PCT/IPEA/409). 11. A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 12. (35 U.S.C. 371 (c)(5)). Items 13 to 20 below concern document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 13. An assignment document for recording A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 14. 15. A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. 16. 17.  $\Box$ A substitute specification. A change of power of attorney and/or address letter. 18. 19.  $\mathbf{X}$ Certificate of Mailing by Express Mail 20.  $\boxtimes$ Other items or information: Return Postcard PTO-2038 Credit Card Payment Form in the amount of \$1,416.00 EL924206043US

INTERNATIONAL APPLICATION U.S. APPLICATION NOGIFACOUNT 19141.0048U2 PCT/US00/16576 CALCULATIONS PTO USE ONLY 21. The following fees are submitted:. BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5)):, Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO \$1,000.00 and International Search Report not prepared by the EPO or JPO. International preliminary examination fee (37 CFR 1.482) not paid to \$860.00 USPTO but Internation Search Report prepared by the EPO or JPO ..... International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$710.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4)..... \$690.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) \$100.00 and all claims satisfied provisions of PCT Article 33(1)-(4)..... ENTER APPROPRIATE BASIC FEE AMOUNT = \$890.00 ⊠ 30 Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e))  $\Box$  20 \$130.00 NUMBER EXTRA RATE CLAIMS NUMBER FILED \$396.00 22 \$18.00 42 - 20 = Total claims \$0.00 \$84.00 0 2 -3 =Independent claims \$0.00 Multiple Dependent Claims (check if applicable). \$1,416.00 TOTAL OF ABOVE CALCULATIONS Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). \$0.00 **SUBTOTAL** \$1,416.00 Processing fee of \$130.00 for furnishing the English translation later than □ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). \$0.00 \$1,416.00 TOTAL NATIONAL FEE Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). \$0.00 \$1,416.00 TOTAL FEES ENCLOSED Amount to be: refunded \$ charged to cover the above fees is enclosed. A check in the amount of to cover the above fees. in the amount of Please charge my Deposit Account No. A duplicate copy of this sheet is enclosed. The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment A duplicate copy of this sheet is enclosed. 14-0629 to Deposit Account No. NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status. SEND ALL CORRESPONDENCE TO: Jennifer P. Medlin, Esq. NEEDLE & ROSENBERG, P.C. 1200 Candler Building Jennifer P. Medlin 127 Peachtree Street, N.E. NAME Atlanta, Georgia 30303 41,385 REGISTRATION NUMBER DATE

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ATTORNEY DOCKET NO. 19141.0048U2 PATENT

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)
KUMAR et al.	) ) Group Art Unit: Unassigned
Serial No. Unassigned	) Examiner: Unassigned
Filed: Herewith	)
FOR: "LIGHT BEAM GENERATION AND FOCUSING DEVICE"	) ) )

### PRELIMINARY AMENDMENT

Commissioner for Patents Box PCT (IPEA/EP) Washington, D.C. 20231 NEEDLE & ROSENBERG, P.C. Suite 1200, The Candler Building 127 Peachtree Street, N.E. Atlanta, Georgia 30303-1811

December 18, 2001

Sir:

Prior to the issuance of an Office Action pertaining to the above-identified patent application, please enter the following preliminary amendment and consider the following remarks.

#### IN THE SPECIFICATION

On page 1 of the specification, before the first paragraph, please insert the following:

-- The present application is a 35 U.S.C. § 371 national phase application from, and claims priority to, international application PCT/US00/16576, filed June 15, 2000 (published under PCT

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Article 21(2) in English), which claims priority to U.S. Provisional Application No. 60/165,814, filed November 16, 1999 and U.S. Provisional Application No. 60/140,003, filed June 18, 1999, which applications are hereby incorporated herein in their entirety.--

### **REMARKS**

The specification is amended herein to update the priority claim for this application. It is believed that no new matter has been added by this amendment, and applicants respectfully request entry of same into the present application.

No fee is believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

Jennifer P/Medlin

Registration No. 41,385

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### **CERTIFICATE OF EXPRESS MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, No EL924206043US an envelope addressed to BOX PCT (IPEA/EP), Commissioner for Patents, Washington, D.C. 20231, on the date shown below.

Erick Calderon

Date

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### LIGHT BEAM GENERATION AND FOCUSING DEVICE

### CROSS REFERENCE TO RELATED APPLICATIONS

The patent application claims priority to, and the benefit of the filing date of, U.S. Patent Application Nos. 60/140,003 and 60/165,814, filed June 18, 1999, and November 16, 1999, respectively.

### FIELD OF THE INVENTION

The invention relates in general to light beam generation and focusing devices, such as laser porators. More particularly, the invention relates to an improved light beam generation and focusing device adapted to emit at least one focused beam of light directed to at least two spaced locations on a surface plane.

### BACKGROUND OF THE INVENTION

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The use of laser porators for forming micropores in the stratum corneum has proven to be an important advancement in the healthcare field. Laser thermal ablation devices, such as that described in U.S. Patent No. 5,885,211, provide a means of quickly and efficiently forming a micropore in the stratum corneum so that interstitial fluids can be easily gathered therefrom for testing the analytes present in the fluid. This has proven to be a very simple yet effective way of testing for glucose, for example. Moreover, the use of laser porators of the type described in the above-referenced patent has led to the development of improved glucose monitoring and testing systems, such as those developed by SpectRx, Inc. of Norcross, Georgia.

When used as a porator for forming micropores in the stratum corneum of a person's skin, the known types of laser ablation devices emit and focus a beam of light at a focal point on the stratum corneum for defining, *i.e.* burning, an opening in the skin layer without penetrating any deeper into the epidermis of the person being tested. Thereafter, interstitial fluids will flow into the opening, or can be drawn into the opening by the use of a separate device, for example, the electro-poration device described in U.S. Patent No. 6,022,316.

Additional laser ablation devices are described in U.S. Patent No. 5,643,252, and in U.S. Patent No. 6,027,496.

What is common to the laser porators of the aforementioned patents, and as illustrated in Fig. 1 hereof, is a laser poration device 5 provided with a light source 6, typically a laser of some type, which laser emits a beam of light directed toward a collimating lens 9. The collimating lens gathers the beam of light and forms it into a columnar beam of light, and directs the beam of light to a spaced focusing lens 11. From the focusing lens, the beam of light is directed toward and focused on a focal point 13 defined on a spaced surface plane.

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U.S. Patent No. 5,643,252 illustrates a laser ablation device of the known type in Figs. 1 and 3 thereof, and also shows in Fig. 5A thereof an ablation device having a spaced arrangement of prisms positioned with respect to the light source for use in splitting the beam of light emitted from the light source into separate beams of light, each beam of light being simultaneously directed to a surface plane. The device of the '252 patent also discloses, in Fig. 5B, a powered acousto-optic modulator for use in creating separate beams of light.

A problem with the known types of laser ablation/poration devices, however, results from the size of the device necessary to emit and focus a beam of light, and the need or desire to form more than one micropore in the stratum corneum of a person being tested.

There is a need, therefore, for a portable laser poration device which can quickly and easily emit at least one focused beam of light directed to at least two spaced focal points on a surface plane spaced from the device. Moreover, there is a need for such an improved device which remains relatively compact, yet flexible enough for use in a variety of applications. There is also a need for an improved laser porator which will more efficiently gather the beam of light emitted from the light source, focus the beam of light, and direct it to the at least two spaced locations on the surface plane.

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### **SUMMARY OF THE INVENTION**

The present invention provides an improved light beam generation and focusing device adapted for use in emitting and directing at least one focused beam of light to at least two spaced locations on a surface plane, which may include the stratum corneum of a person, and which overcome some of the design deficiencies of the known art. The light beam generation and focusing device of this invention provides a simple and efficient device which allows for a greater degree of flexibility in use when compared to the known types of laser porators. Moreover, the relative simplicity of the device of this invention, when contrasted with the known laser porators, addresses the problems of efficiently and cost effectively focusing at least one beam of light on a surface plane for defining an opening therein, and more preferably for defining an opening in at least two spaced locations therein.

The invention attains this degree of flexibility, as well as simplicity in design and construction, by providing an improved light beam generation and focusing device having a light source constructed and arranged to emit at least one beam of light, a lens assembly constructed and arranged to focus the at least one beam of light on the surface plane, and which is also constructed and arranged to direct the at least one beam of light to at least two spaced locations on the surface plane.

The lens assembly of the device comprises a collimating lens positioned with respect to the at least one beam of light, and a focusing lens spaced therefrom. The collimating lens may comprise a micro-lens, and more particularly may comprise a cylindrical micro-lens mounted directly to the light source. The light source may comprise a laser diode, and may further comprise a single active element laser diode chip, or multiple active element laser diode chips.

The device may also include, in one embodiment, a beam steering device constructed and arranged to direct the at least one beam of light to the at least two spaced locations on the surface plane. The beam steering device

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includes a beam steering optical element, and a drive motor, or drive motors, for moving the optical element so as to direct the at least one beam of light from a first location on the surface plane to a spaced second location thereon. The drive motor(s) may comprise a stepper motor, or other motors designed to function similarly.

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The beam steering optical element may comprise a wedge prism or a tilted or angled plane in a first embodiment, each of which is driven by the drive motor. The optical element may also comprise a holographic or a diffractive optical imaging element in a second embodiment thereof such that a motor is not required, the optical element serving both to split the optical energy, *i.e.* the at least one beam of light, and to direct the at least one beam of light to the at least two spaced locations on the surface plane.

In another embodiment of the invention, the light beam generation and focusing device will be sized and shaped to fit within the hand of the device user, and will comprise a power supply, a light source, and a beam steering device fitted within the housing for directing the at least one beam of light emitted therefrom to the at least two spaced locations on the surface plane, or alternately may comprise at least two separate light sources within the housing, *i.e.*, two separate laser diodes, used to emit separate beams of light.

Accordingly, in still another embodiment of the invention, the light source will comprise at least two laser diodes mounted on a common mounting block. Each of the laser diodes will preferably comprise a laser diode chip, although other types of suitable light emitting sources may be used. Each laser diode chip will be spaced approximately eight hundred (800) microns apart from each adjacent one of the laser diode chips for forming a predetermined pattern of light beams directed toward the surface plane.

The device also includes a controller/microprocessor coupled to the light source and/or to the beam steering device, where one is provided, for controlling the emission of the at least one beam of light, and for directing the

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at least one beam of light to the at least two spaced locations on the surface plane.

An improved method of emitting a focused beam of light directed to a surface plane results from the unique construction of this invention, the method including the steps of emitting at least one beam of light from a light source, passing the at least one beam of light through a lens assembly for being focused on the surface plane, and sequentially directing the at least one beam of light to at least two spaced locations on the surface plane with the device.

The step of sequentially directing the at least one beam of light may include the step using a beam steering device, or using at least two spaced light sources. Moreover, the method may include the step of sequentially directing the at least one beam of light to at least four spaced locations on the surface plane for forming a predetermined pattern thereon.

The objects, features, and advantages of the present invention will become apparent upon reading the specification, when taken in conjunction with the accompanying drawings, to which the invention is directed.

### **BRIEF DESCRIPTION OF THE DRAWINGS**

- Fig. 1 is a schematic illustration of a known type of laser poration device.
- Fig. 2 is a schematic illustration of a first embodiment of the light beam generation and focusing device of this invention.
  - Figs. 3A and 3B are schematic illustrations of a second embodiment of the light beam generation and focusing device of this invention.
- Fig. 4 is a schematic illustration of the light beam generation and focusing device of Figs. 3A and 3B.
  - Fig. 5 is a schematic illustration of a combined light source and lens assembly for use with the light beam generation and focusing device of this invention.

Figs. 6A-6C illustrates three separate embodiments of a beam steering optical element that may be used as a part of the beam steering device of the invention.

Fig. 7 is a partial schematic perspective illustration of a third embodiment of the light beam generation and focusing device of this invention.

Fig. 8 is a partial exploded schematic view of the embodiment of the light beam generation and focusing device of Fig. 7.

Fig. 9 is a schematic illustration of the light beam generation and focusing device of Figs. 7 and 8.

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Fig. 10 is a schematic side elevational view along line 10-10 of Fig. 7.

Fig. 11 is a schematic illustration of a fourth embodiment of the light beam generation and focusing device of this invention.

Fig. 12 is a schematic illustration of a fifth embodiment of the light beam generation and focusing device of this invention.

Fig. 13 is a circuit diagram of the control circuit used in connection with the embodiments of the light beam generation and focusing device of Figs. 2-12.

### **DETAILED DESCRIPTION OF THE INVENTION**

20 Referring now in detail to the drawings, in which like reference characters indicate like parts throughout the several views, a first embodiment of the light beam generation and focusing device of 15 of this invention is illustrated in Figs. 2 and 5. The device 15 is provided with a light source 16, here a suitable laser diode, for example those laser diodes manufactured by High Power Devices, or other laser diodes, also referred to as semiconductor diode lasers.

The light source 16 will preferably be a low-cost solid state laser diode capable of delivering a beam a light having an emission wave length of approximately eight hundred nanometers, or at such other wave lengths and power levels necessary for the intended purposes, which may include, but are

not limited to, the forming of a micropore in the stratum corneum of a person's skin. Also, it is anticipated that the laser diode will be sized such that it will be sufficiently small so as to be portable enough to fit within a hand-held housing. Although not shown in Figs. 2 and 5, the light source 16 will be powered by a suitable power source 25, which may include batteries, including, but not limited to, lithium, lithium-ion, nickel-metal hydride, and nickel-cadmium batteries; a capacatively charged power source, for example a storage capacitor; or a regulated wall type power supply capable of converting an electrical line voltage into the voltage needed to operate the device.

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As shown in Figs. 2-5, the light source 16 is fitted with a collimating lens 17 mounted directly to the light source. It is envisioned that the collimating lens 17 will comprise a micro lens, and may also therefore include a cylindrical micro-lens adapted to gather the light emitted from the light source 16, and to collimate the light so that it is emitted therefrom as an aligned and oriented beam of light directed toward a spaced focusing lens 19. The focusing lens will direct the beam of light toward a focal point 21 defined on a spaced surface plane "S", which is any desired surface plane, to include the stratum corneum of a person, or any other surface on which the beam of light is to be focused.

Fig. 5 illustrates an alternate embodiment of the arrangement of the device 15 shown in Fig. 2, in that the focusing lens 19 is affixed to a casing 23, the casing in turn being affixed to the light source 16 along with the collimating lens 17 so that the light source and lens assembly are formed as one compact assembly designated by the reference character "L." The construction shown in Fig. 5 offers a compact and efficient arrangement which is advantageous for use in a hand-held light beam generation and focusing device.

A second embodiment of the light beam generation and focusing device 15 is illustrated in Figs. 3A & B, and in Fig. 4. In this embodiment of the device the light source 16 is again provided with a collimating lens 17, a micro-lens, fitted directly to the light source, with a spaced focusing lens 19 for focusing the beam of light 20. However, and unlike the first embodiment of this

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invention, the device 15 includes a beam steering device 28 constructed and arranged to receive the focused beam of light, and to direct the beam of light to at least two spaced locations on the surface plane. This is accomplished by positioning a beam steering optical element 29 between the focusing lens 19 and the surface plane S, such that the beam steering optical element intercepts the focused beam of light, and selectively directs the beam of light to a first focal point 21 on the surface plane, and then to at least a second spaced focal point 21 on the surface plane, shown in broken lines.

The beam steering device will include in a first embodiment thereof a drive assembly 31, best shown in Figs. 3A and 3B, comprised of a drive motor 32, here a stepper motor, a mounting collar 33 for mounting the stepper motor to the casing 23 of the light source 16, a gear train 35 having a drive gear 35' rotated by the stepper motor 32, a driven gear 35" affixed to the beam steering optical element 29, and a motor controller 36 for operating the stepper motor so that it will move the beam of light 20 from the first focal point 21 to at least the second spaced focal point 21', as shown in Fig. 4. Although not shown, it is envisioned that more than one drive motor may be provided as a part of the beam steering device.

Referring now to Figs. 3A and 3B, the light beam generation and focusing device 15 includes a hand-held housing 24 in which the device is fitted. The housing is sized and shaped to fit within the hand of the device user, and is provided with a suitable power supply 25, as described above. It is preferred, although not required, that the power supply be battery powered, and more preferably, that it be one of the known types of rechargeable batteries.

As shown in Figs. 3A and 3B, the device 15 will include the compact collimating lens assembly shown in Fig. 5, which assembly will have the beam steering device 28 fitted thereto by the mounting collar 33 as described above. A controller 27, also referred to herein interchangeably as a microprocessor or microcontroller, is provided as a part of the device, and is positioned within the

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housing 24 for controlling the light source such that a pulsed laser beam is generated and emitted therefrom, and which also signals a motor controller 36 for controlling the operation of the beam steering device drive motor.

The construction of the controller 27 and of the motor controller 36 is not shown in greater detail as these are otherwise conventional control or microprocessor chips adapted for use in both controlling the operation of the light source 16, as well as operating the motor 32. Each of the controller 27 and the motor controller 36, as well as the controller 64 described hereinbelow, therefore comprises a conventional microprocessor available from a variety of vendors/manufacturers in known constructions, and which will either be preprogrammed or programmable, as known, and will also be provided with a memory or access to a memory storage and retrieval device.

Moreover, although a stepper motor 32 is disclosed herein for use in driving the beam steering optical element 29, it is understood by those skilled in the art that any suitable motor, or controllable actuator, including, but not limited to a servomotor, a solenoid, a pneumatic cylinder, a hydraulic cylinder, or the like, could be used for this purpose, as desired. A stepper motor is preferred here for its ability to precisely control the movement of the beam steering device.

The actual physical construction of the device 15 shown in Figs. 3A and 3B is not discussed in greater detail for the reason that the manner and method of assembling the components is well known, and will comprise the use of a PC board to which the controllers 27 and/or 36 will be affixed, and to which the power supply 25 will also be connected through the known types of electronic circuits, as is the light source 16.

Although, the device 15 shown in Figs. 3A and 3B uses the compact light source and lens assembly L shown in Fig. 5, it is also envisioned that the device could use conventional spaced collimating and focusing lenses which are not affixed to or mounted on the light source 16 and the casing 23,

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respectively, as shown, for example, in U.S. Patent No. 5,885,211 to *Eppstein et al.*, the provisions of which are incorporated fully herein by this reference.

Moreover, although the beam steering optical element 29 shown in Fig. 4, as well as in Fig. 6A is an inclined optical plane 38, it is anticipated that other embodiments of the beam steering optical element may be used, as shown in Figs. 6B and 6C. Referring now to Fig. 6B, the beam steering optical element 29 may comprise a wedge shaped prism 39 positioned anywhere in the optical beam path, but which is preferably positioned between the focusing lens (not shown) and the focal point 21 on the surface plane (Fig. 4). The prism 39 will be moved by the drive motor 32, the prism being held by a suitable support structure or framework with respect to the light source 16 of Figs. 2-5. Both the optical plane and the prism will be rotated about a central axis "A" positioned coaxially with the axis of the light source for directing the beam of light to the at least two spaced locations 21, 21', on the surface plane.

The optical plane 38 comprises a tilting, flat optical window, or plate, which may be positioned between either the light source and the collimating lens, or between the focusing lens and the surface plane. The focal point of the beam of light can thereby be steered by tilting this flat optical window in the x and y dimensional planes, where the thickness of the window affects the beam of light via refraction of the light beam leading to a lateral translation of the focal point in an amount related to the degree of tilt in the desired direction. The steering of the beam of light in this fashion offers some cost advantages over an optical wedge in that an optical window/plane is a simpler element to fabricate.

Each of the optical plane 38 of Figs. 4 and 6A, and the prism 39 of Fig. 6B comprise an optical quality glass or plastic element, respectively, the plane 38 being a plate or sheet of glass or plastic, whereas the prism 39 will shaped as a prism of any suitable construction or configuration. All that is required is that the plane 38, prism 39 be suitable for bending light to be incident at the required distance from the optical axis, and be provided with suitable

transmissability and anti-reflective coatings at the desired wavelengths. The optical plane of Figs. 4 and 6A is mounted in an inclined fashion in a holder, while the prism is mounted in an erect manner.

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Yet another embodiment of the beam steering device 28 is shown in Fig. 6C, which embodiment does not utilize the drive assembly 31 of Figs. 3A and 3B. Instead, a holographic or diffractive optical element 40 is used which masks the beam of light received from the upstream light source, such that discrete beams of light 20 are passed toward the surface plane to the separate focal points 21, 21" thereon. This type of holographic or diffractive imaging into multiple focal points is preferably done using a monochromatic light source, such as a laser diode. Additionally, when using these types of holographic or diffractive optical elements, to ensure an equal distribution of optical energy to the various focal points, it is preferable to mask the first order image and use only the multiple second order images emitted from the element.

Although, reference has been made hereinabove to a first focal point 21 and a second focal point 21', or 21", respectively, it is envisioned that the beam steering embodiments of the device 15 will be used to direct the beam of light to at least two, and as many more spaced locations/focal points on the surface plane as desired. A preferred light pattern here is shown as having four spaced focal points on the surface plane spaced at least eight hundred microns apart from one another for defining a predetermined pattern of focal points, or openings if the device is being used to define a plurality of micropores through the stratum corneum and into the viable layers of the epidermis of a person. The beams of light emitted from the device, in each of its several embodiments, will preferably penetrate to a depth of at least 80 to 100 microns beneath the outermost surface of the skin layers. This type of construction is desirable for allowing the interstitial fluids to be collected from a plurality of closely grouped micropores for expediently testing the interstitial fluids for analytes or for any other desired purpose(s).

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It is envisioned, therefore, that the beam(s) of light can be formed into any type of geographic pattern capable of being defined on a surface plane, which may thus include a hexagonal shaped pattern, a rectangular pattern, a circular pattern, or a pattern of any desired type, based upon the operating program stored within the controller 27 and/or the motor controller 36 of the device, all as desired by the end user of the device, based on the known types of programmable control/microprocessor chips available in the art, and the known methods of programming same.

A fourth embodiment of the light beam generation and focusing device 50 is illustrated in Figs. 7-9. Referring first to Figs. 7 and 8, in this embodiment of the invention, rather than using a beam steering device 28 as shown in Figs. 3A - 4, a plurality of light sources 51, again laser diodes as described above, are mounted to a common mounting block 52 in the desired geometric pattern to be defined on the surface plane of Figs. 10-12. Each one of the light sources 51 will be mounted on the mounting block, which also functions as either a ground or an electrode, by an insulated wire bonding pad 54 for forming either the anodic or cathodic lead for the laser diode, respectively, whereas the respective cathodic/anodic leads will be formed through the known wire bonding techniques. The emitting facets of the respective laser diodes will preferably be aligned along the "z" dimensional axis such that when collimated and re-imaged to focus on the surface plane, the focal point of each individual laser diode will lie on the common surface plane.

Each of the insulated wire bonding pads 54 will be separately positioned within a respective one of the depressions 54' defined within the mounting block, with the laser diodes being soldered or otherwise bonded to the heatsink and wired to the bonding pads, and thus to the mounting block 52. The wire bonding pads are insulated from the mounting block so that the block can provide the "opposite" electrical supply, be it positive, or negative, as desired. The mounting block, be it a common ground or a common positive, will

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preferably comprise a block of high thermal conductivity copper, or other high quality thermally conductive heatsink materials.

Four spaced light sources 51, illustrated in Fig. 7 as four separate laser diodes, together define a predetermined pattern shown by the broken lines as designated by the reference character "D". Each of the respective laser diodes will be spaced approximately eight hundred microns apart from each adjacent laser diode within this predetermined pattern. Here, rather than emitting a single beam of light with a single light source and then "steering" the beam of light, a plurality of separate light beams, in this instance four light beams, will be emitted from the device in sequential fashion toward the surface plane S. This eliminates, entirely, the need for any kind of mechanical device interposed between the respective light sources 51 and the surface plane. As with the beam steering embodiment of the invention, the beams of light emitted from the respective light sources are capable of being formed into any type of geographic pattern capable of being defined on a surface plane, as governed by the mounting pattern of the laser diodes on the mounting block.

Referring now to Fig. 9, the construction of the light beam generation and focusing device 50 is described in greater detail. The device 50 is provided with four light sources 51, each of which comprises a laser diode, for example a single active element laser diode chip. Each laser diode is affixed to the mounting block 52 as an assembly 51A. The assembly fits within a lens holder 55, to which a lens assembly 56 is fitted. The lens assembly 56, as shown in Fig. 9, includes a collimating lens 58 and a spaced focusing lens 59. A casing 60 is fit over the lens assembly 56, and hold the lens assembly in position with respect to the lens holder 55 and the laser diode assembly 51A.

The casing 60, lens assembly 56, and laser diode assembly 51A are fitted within a housing 62, the housing being sized and shaped to be held within the hand of a user. A suitable power supply 63 is provided within the housing, this being the same type of power supply as is power supply 25, described above.

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The device 50 will include a controller/microcontroller 64, a known type of microprocessor, as described hereinabove, and is provided with a resistor pin network 66 which provides a series of pull down resistors used to prevent the lasers from firing without the proper actuating command. The device 50 also includes a three pin header 67, provided as a programming port for the controller 64, in known fashion. The controller 64, as well as the resistor network 66, and the header 67 are fit within an electronics compartment defined within the housing, with an electronics compartment cover 68 fitted thereto for enclosing the electronics controls of the device within the housing.

Still referring to Fig. 9, a plurality of spaced pogo pins 70 are provided for connection to the power supply 63, assuming the power supply comprises batteries, as described hereinabove, batteries being preferred for providing ease of portability in the use of the device. The housing is also provided with a power switch 71 for operating the device, and includes a plurality of conventional fasteners 72 for affixing the laser diode assembly 51A to the housing, and a plurality of fasteners 74 for affixing the electronics compartment cover to the housing as well. The device 50 is also provided with a bi-color LED 75 for the purpose of indicating a ready status in which the device is charged and ready for use, and a firing status indicating that the light source, the laser diode or diodes, are firing. For example, a flashing green light may be used to indicate the ready status, and a flashing red or amber light to indicate that the device is firing, and to meet the appropriate BRH/FDA laser safety warning requirements.

Referring now to Fig. 10, the embodiment of the device shown in Figs. 7-9 is shown in a schematic side elevational view. Two spaced light sources 51, a pair of laser diodes, are shown affixed to the mounting block 52. Each light source emits a separate beam of light 20 toward a first collimating lens 58, which gathers and collimates the light, and passes it to a spaced downstream focusing lens 59, such that the beams of light are separately focused at focal points 21, 21' on the surface plane. Again, although only two focal points are

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shown, it is understood by reference to Figs. 7 and 8, that there will be at least four such focal points formed into the shape of a predetermined pattern on the surface plane.

The device of Fig. 10 may be used with any conventional lens assembly, such as that shown in Fig. 9, and comprising lens assembly 56. However, the embodiment of light beam generation and focusing device 50 shown in Figs. 7-10 may also be used with the micro-lens construction of the device shown in Figs. 2-5, such that, and as shown in Fig. 11, a micro-lens 77 is affixed to each light source/laser diode 51 for gathering and collimating the respective light beams, and passing the light beams to a spaced focusing lens 59, which then passes the light beams to two separate focal points 21, 21'.

If full advantage of the construction shown in Figs. 2-5 is to be achieved, then the construction of Fig. 12 results, in which each one of the light sources 51 is provided with a compact lens assembly and casing as shown in Fig. 5, such that the micro-lens is affixed directly to the laser diode, and a casing is also affixed to the laser diode, whereupon the focusing lens is affixed to the casing so that no separate collimating and focusing lens assemblies are needed for focusing and directing the separate beams of light 20 towards the focal points 20, 21' on the surface plane.

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In the embodiment of the light beam generation and focusing device shown in Figs. 2-6, the construction of the device, namely there being a beam steering device 28 provided as a part thereof, results in the sequential direction of a focused beam of light to at least two, and more preferably four, spaced focal points 21 on the surface plane. In particular, for the embodiments of the device shown in Figs. 6A and 6B, a stepper motor and a focal plane 38 and/or a prism 39 are used to steer the beam of light. As it necessary to physically move the beam steering optical element 29 for directing the beam of light 20 to any separate one of the different focal points 21, 21', and so on defined on the surface plane, the direction of the beam of light must necessarily be done in

sequence with a first focal point being established, and with any and all subsequent focal points being established in sequential order.

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For the embodiment of the device 15 shown in Fig. 6C, using the holographic or diffractive optical element 40, and which does not otherwise use a drive motor as a part of the beam steering device, it is possible that the beam of light may be simultaneously directed to the several focal points formed on the surface plane. If, however, and not illustrated but envisioned, the holographic/diffractive element is used in combination with a beam steering device positioned between the light source 16 and the downstream holographic plate, then the focal points would be established sequentially, all as desired, and as programmed into the controller 27 of the device.

With regard to the embodiment of the device illustrated in Figs. 7-12, however, still greater flexibility results from the construction of the device in that the controller 64 will preferably operate each of the four light sources/laser diodes 51 sequentially for emitting separate beams of light from each respective laser diode toward the surface plane. However, due to the construction of the device shown in Figs. 7-12, it is also possible that the controller 64 could be programmed so that each one of the light sources 51 fires simultaneously, although this is not preferred when compared to sequential operation of the device in that the peak power drain on the battery of the device would be much greater than from sequential operation. Also it is possible that if all of the laser diodes of the device were operated simultaneously the device would heat up more quickly, requiring a greater cooling capacity for the mounting block 52, and there would likely be a noticeable discomfort factor for the person on whose stratum corneum, for example, the multiple light beams were focused as the surface plane.

Referring to Fig. 13, a control circuit 100 is shown which may be used to operate either the stepper motor for the beam steering device 28 (Figs. 3A-4, 6A-6B) or to drive the multiple lasers in the embodiment shown in Figs. 7-12. The control circuit 100 comprises a programmable controller 110, the power

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switch 71 (referred to above), and a plurality of laser drive circuits 120. In addition, the circuit 100 drives status indicators 130 and 132 (referred to above) which are, for example, the bi-colored light emitting diodes (LEDs) 75. Each laser drive circuit 120 comprises a field effect transistor (FET) 122 that act as a high current switch to activate a corresponding one of the light sources 51. The light sources 51 are, for example, laser diodes. A diode 124 is included in each laser drive circuit 120 to provide protection for the light sources 51 in the event a static discharge occurs. The parallel resistor-capacitor combination in each laser drive circuit 120 acts as a filter for pulse smoothing and to reduce electrical switching spikes that may occur when the control circuit 100 is powered on.

The controller 110 is, for example, a programmable micro-controller and is programmed to time the on/off time signals coupled to the laser drive circuits 120 for sequencing the operation of the light sources 51. For example, four of the pins may be programmed to the proper sequence of time on vs. time off to drive the drive (stepper) motor for the beam steering device 28. Alternatively, four of the pins may be programmed to the proper sequence of time on vs. time off to power the field effect transistors which act as the high current switches used to turn the light source(s), here laser diodes, on and off in the desired sequence. The outputs of the controller 110 that is coupled to the laser drive circuits 120 are found at pins 11-14 thereof.

The signal on each of these pins is coupled to the gate of a FET 122 of a corresponding laser drive circuit 120, and causes the desired time on vs. time off for a light source. The controller 110 also drives the status indicators 130 and 132 according to the status of the signals on pins 11-14. Programming of the controller 110 is achieved by a suitable programming interface 112 that supplies programming signals to pins 3 and 4 of the controller 110.

The controller 110 is also programmable to generate similar timing signals at pins 11-14 to drive a stepper motor in the beam steering device 28 shown in Figs. 3A-4, 6A-6B, thereby controlling the location of the laser beam.

Although, several embodiments of the invention have been disclosed in the foregoing specification, it is understood by those skilled in the art that many modifications and other embodiments of the invention will come to mind to which the invention pertains, having the benefit of the teaching presented in the foregoing description and associated drawings. It is thus understood that the invention is not limited to the specific embodiments disclosed herein, and that many modifications and other embodiments of the invention are intended to be included within the scope of the appended claims. Moreover, although specific terms are employed herein, as well as in the claims, they are used in the generic and descriptive sense only, and not for the purposes of limiting the described invention, nor the claims which follow.

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#### WE CLAIM:

1. A light beam generation and focusing device for directing at least one focused beam of light at a surface plane, said device comprising:

a light source constructed and arranged to emit at least one beam of light; and

a lens assembly constructed and arranged to focus said at least one beam of light on the surface plane;

said device being constructed and arranged to sequentially direct the at least one beam of light to at least two spaced locations on the surface plane.

- 2. The device of claim 1, said lens assembly comprising a collimating lens positioned with respect to the at least one beam of light and a focusing lens spaced from the collimating lens.
- 3. The device of claim 2, said collimating lens and said focusing lens each comprising a fresnel lens.
- 4. The device of claim 2, said collimating lens comprising a micro lens.
- 5. The device of claim 4, said micro lens comprising a cylindrical micro lens.
- 6. The device of claim 4, said micro lens being mounted to said light source.

- 7. The device of claim 1, said light source comprising at least one laser diode.
- 8. The device of claim 7, said at least one laser diode further comprising a semiconductor laser diode chip.
- 9. The device of claim 7, said lens assembly having a micro lens affixed to said at least one laser diode and through which said at least one beam of light passes.
- 10. The device of claim 9, said micro lens comprising a cylindrical micro lens.
- 11. The device of claim 7, comprising a casing within which said at least one laser diode is positioned, said lens assembly comprising a focusing lens affixed to said casing and spaced from said at least one laser diode.
- 12. The device of claim 11, said lens assembly further comprising a collimating lens affixed to said at least one laser diode, said focusing lens being spaced from said collimating lens.
- 13. The device of claim 1, comprising a beam steering device constructed and arranged to direct said at least one beam of light to said at least two spaced locations on the surface plane.
- 14. The device of claim 13, said beam steering device comprising a beam steering optical element and a drive means for moving said optical element so

that said at least one beam of light is directed from a first location on the surface plane to a second spaced location thereon.

- 15. The device of claim 14, said drive means comprising a stepper motor, said optical element being selected from one of the group of optical elements consisting of a wedge prism and a tilted or angled plane.
- 16. The device of claim 15, further comprising a motor controller coupled to said stepper motor for control the movement of said beam steering device.
- 17. The device of claim 13, further comprising a controller coupled to said beam steering device, said controller being constructed and arranged to control the movement of said beam steering device to sequentially direct said at least one beam of light to said at least two spaced locations on the surface plane.
- 18. The device of claim 13, said beam steering device comprising a beam steering optical element, said optical element being selected from one of the group of optical elements consisting of a wedge prism, a tilted or angled plane, and a holographic plate.
- 19. The device of claim 1, said device being constructed and arranged to sequentially direct the beam of light to at least four spaced locations on the surface plane in a predetermined pattern.
- 20. The device of claim 19, said at least four spaced locations on the surface plane defining a predetermined pattern thereon.

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- 21. The device of claim 19, each of the at least four spaced locations on the surface plane being spaced approximately eight hundred microns from each adjacent one of said at least four spaced locations thereon.
- 22. The device of claim 1, said light source and said lens assembly being fitted within a housing sized and shaped to fit in the hand of a device user.
- 23. The device of claim 22, further comprising a power supply within said housing for powering said light source.
- 24. The device of claim 22, further comprising a beam steering device positioned within said housing with respect to said light source, said beam steering device being constructed and arranged to direct said at least one beam of light to said at least two spaced locations on the surface plane.
- 25. The device of claim 24, further comprising a controller within said housing, said controller being operably coupled to said power supply, said light source, and said beam steering device, for triggering the emission of said at least one beam of light from said light source and for directing said at least one beam of light to said at least two spaced locations on the surface plane.
- 26. The device of claim 22, said light source comprising at least two laser diodes mounted to a mounting block positioned within said housing.
- 27. The device of claim 26, further comprising a controller coupled to each of said at least two laser diodes and adapted to sequentially operate each said laser diode with respect to the other for directing the beam of light to said at least two spaced locations on the surface plane.

- 28. The device of claim 1, said light source comprising at least two laser diodes mounted on a mounting block.
- 29. The device of claim 28, said light source comprising four spaced laser diodes mounted on a common mounting block.
- 30. The device of claim 29, each of said at least two laser diodes comprising a single active element laser diode chip.
- 31. The device of claim 30, each said laser diode chip being spaced approximately eight hundred microns from each adjacent one of said laser diode chips.
- 32. The device of claim 30, said laser diode chips being spaced apart from one another to form a predetermined pattern of beams of light directed to the surface plane.
- 33. The device of claim 28, comprising a microcontroller coupled to each said laser diode and adapted to sequentially operate each said laser diode with respect to one another for emitting said at least one beam of light and for sequentially directing said at least one beam of light to said at least two spaced locations on the surface plane.
- 34. The device of claim 28, said mounting block comprising a copper mounting block having a first planar surface, a spaced parallel second planar surface, and a plurality of sides adjoining one another and each said planar surface along their respective common edges.

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- 35. The device of claim 34, each of said at least two laser diodes being mounted to a separate one of the sides of said mounting block.
- 36. The device of claim 34, comprising a separate insulated wire bonding pad on said mounting block for each respective one of said at least two laser diodes.
- 37. The device of claim 1, comprising a controller constructed and arranged to sequentially direct said at least one beam of light to said at least two spaced locations on the surface plane.
- 38. A method of generating a focused light beam directed to a surface plane, comprising:
  - a) emitting at least one beam of light from a light source;
  - b) passing the at least one beam of light through a lens assembly and focusing said at least one beam of light on the surface plane in response thereto; and
  - c) sequentially directing the at least one beam of light to at least two spaced locations on the surface plane.
- 39. The method of claim 38, comprising the step of directing the at least one beam of light to a first location on the surface plane and then to a spaced second location thereon using a beam steering device.

- 40. The method of claim 38, comprising the step of emitting at least two separate beams of light toward the surface plane using at least two spaced laser diodes.
- 41. The method of claim 38, comprising the step of sequentially directing the at least one beam of light to at least four spaced locations on the surface plane in a predetermined pattern.
- 42. The method of claim 41, comprising the step of directing the at least one beam of light to each of said at least four spaced locations on the surface plane so that each said location is spaced approximately eight hundred microns from each adjacent one of said spaced locations.

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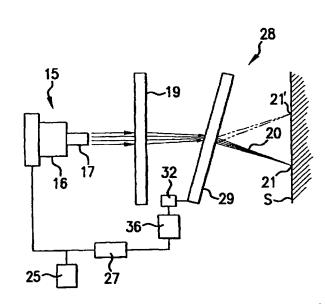
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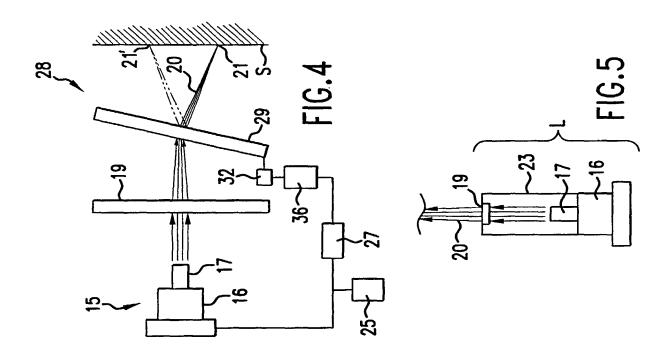
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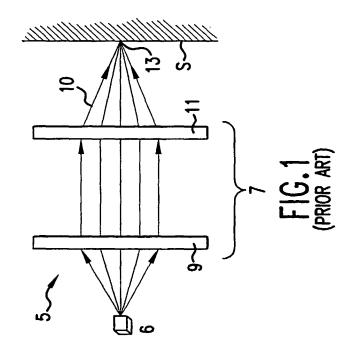
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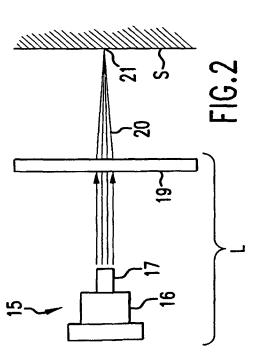


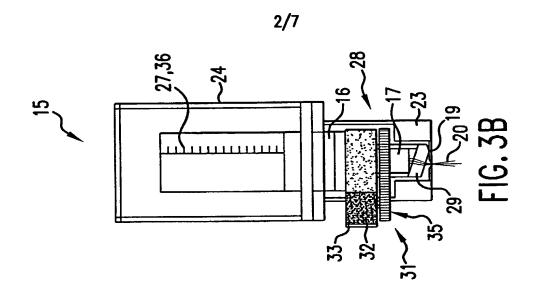
(57) Abstract: An improved light beam generation and focusing device (15, 50) is disclosed. The device has a light source (16, 51) constructed and arranged to emit at least one beam of light (20), and a lens assembly (17, 19, 56) constructed and arranged to focus the at least one beam of light on a surface plane. The device is constructed and arranged to sequentially direct the at least one beam of light to at least two spaced locations (21, 21') on the surface plane. The lens assembly comprises a collimating lens (17), and a spaced focusing lens (19). The collimating lens may comprise a micro-lens, and more preferably a cylindrical micro-lens mounted on the light source. In a first embodiment, the device is provided with a beam steering device (28) having a beam steering optical element (29), and a drive assembly (31) for actuating the beam steering optical element such that the at least one beam of light is directed to the at least two spaced locations on the surface plane. In a second embodiment, the device is provided with a plurality of light sources mounted to a mounting block (52), each light source emitting a separate beam of light to separate focal points, respectively, on the surface plane.

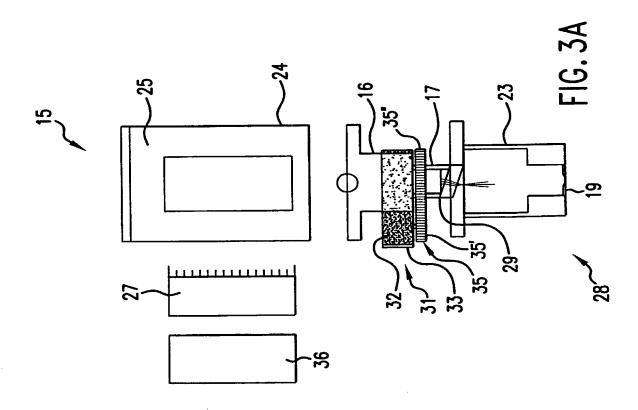
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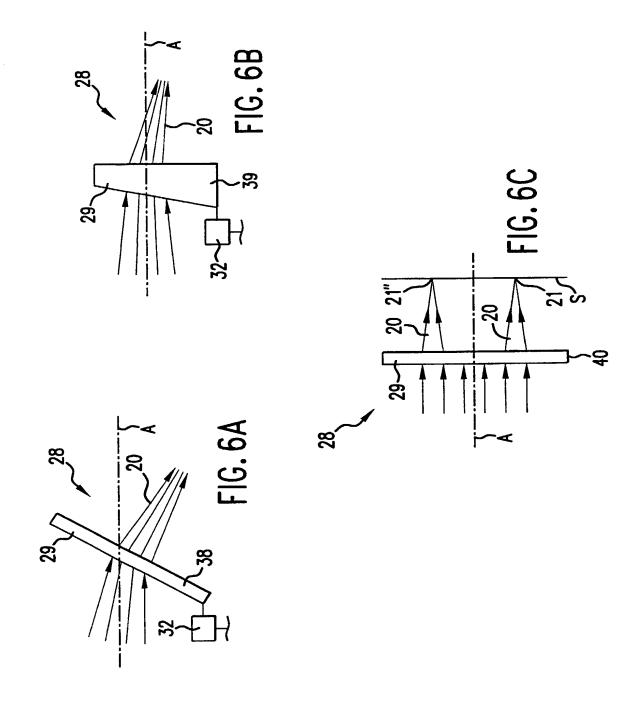




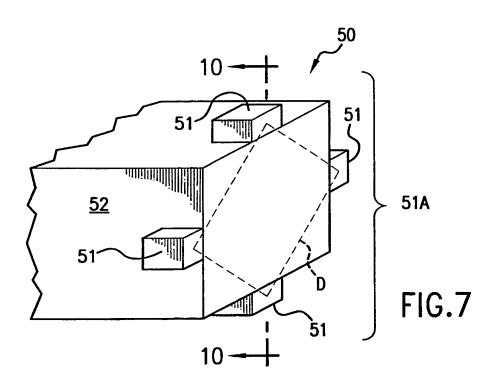


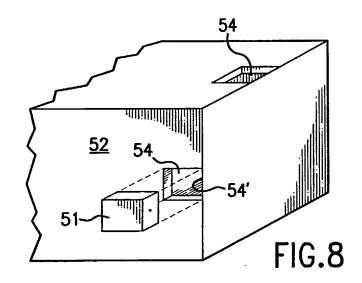


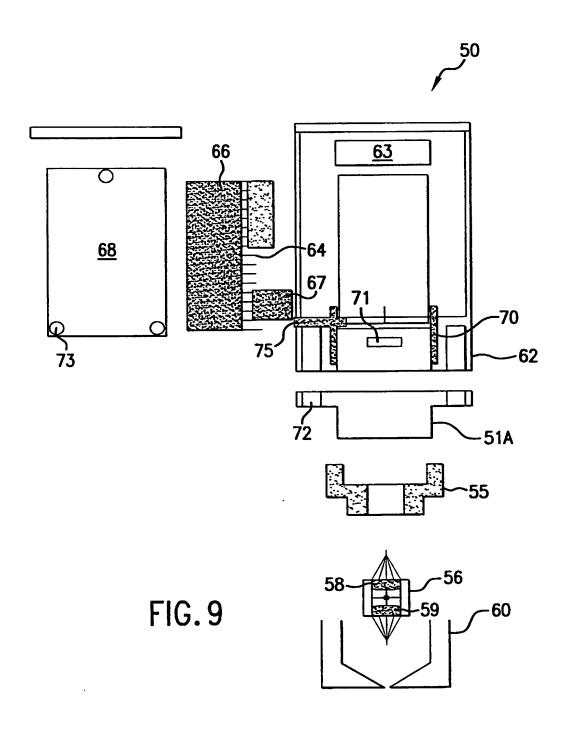


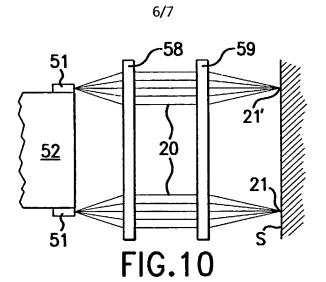


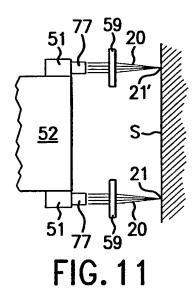
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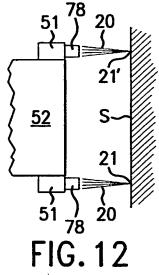




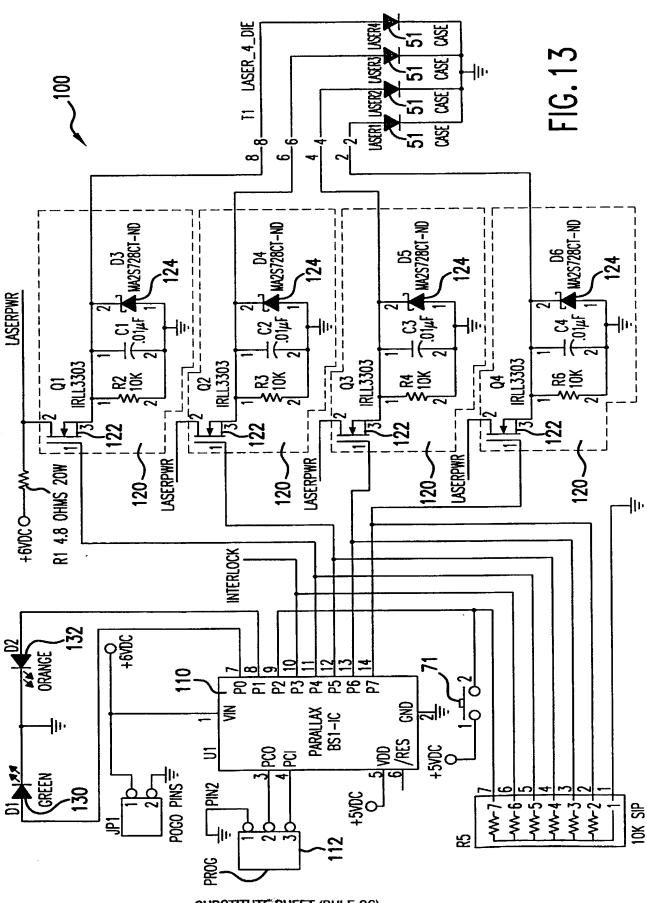








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### DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

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As a below n	amed in	ventor, I hereby declare that:		
My residence	, post o	ffice address and citizenship are	as stated below next to n	ny name.
joint inventor patent is soug	r (if plur ght on th	ginal, first and sole inventor (if or ral names are listed below) of the ne invention entitled "LIGHT BY described and claimed in the spec	subject matter which is EAM GENERATION A	claimed and for which a
(check one)	[ ] [ ] [X]	which is attached hereto, or which was filed on, as United S through (if applicable), or in International Application No amended on (if applicable).	• •	
•		ave reviewed and understand the as amended by any amendment		entified specification,

I acknowledge the duty to disclose all information known by me to be material to the patentability of the claims of this application in accordance with Title 37, Code of Federal Regulations, §1.56.

I hereby claim foreign priority benefits under Title 35, United States Code §119 (a)-(d) or §365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) or §365(b) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

ll .	. FOREIGN APP TER BELOW IF AP	·		Y CLAIMED NATE BOX BELOW)
APP. NUMBER	COUNTRY	DAY/MONTH/YEAR FILED	YES	МО
PCT/US00/16576	РСТ	15 June 2000	X	

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below.

APPLICATION NUMBER	FILING DATE
60/165,814	16 November 1999
60/140,003	18 June 1999

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information known by me to be material to the patentability of the claims of this application as defined in Title 37, Code of Federal Regulations, §1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION SERIAL NO.	FILING DATE	(MARK	STATUS appropriate coli	JMN BELOW)
		PATENTED	PENDING	ABANDONED

I hereby appoint the following attorneys and/or agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:



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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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